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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,695	09/30/2003	Robin D. Pierce	12008.125US01	5085

7590 10/04/2007
MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903

EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1795

MAIL DATE	DELIVERY MODE
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10/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/674,695

Applicant(s)

PIERCE ET AL.

Examiner

Kaj K. Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,6-16,18 and 21-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-16 and 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The examiner noticed that the drawings appear to have been last modified on 12-13-2004 to which the examiner objected to new fig. 7 in the office action dated 3-3-2005. In applicant's next response on 5-5-2005, applicant deleted the additions to the specification concerning all the new figures, but does not appear to have actually cancelled the new figures. If applicant wishes to revert back to the previous figures, it is the examiner's understanding that the applicant must replace the objected-to figures with the previous figures. See MPEP 608.02(f). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 3, 6-16, 18 and 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feldman and Gilmartin with or without evidence from Hedenmo et al (Analyst, 121, 1996, pp. 1891-1895) or Karube et al (USP 5,804,047).

4. Feldman discloses a biosensor (col. 1, ll. 13-14) having: an electrode support (col. 26, ll. 25-26 and Fig. 2, 38); an arrangement of electrodes disposed on the electrode support, the arrangement of electrodes comprising at least a working electrode and at least a second electrode (col. 26, ll. 22-23 and Fig. 2, 22 and 24); a first conductive track leading from the working electrode to an electrical contact associated with the working electrode and a second conductive track leading from the second electrode to an electrical contact associated with the at least second electrode (Fig. 2, 22 and 24); and at least one reagent incorporated in the working electrode (col. 21, ll. 28-31) comprising an enzyme (col. 24, ll. 18-43) and a mediator (col. 15, ll. 20- col. 24, ll. 15). Specifically, the enzyme can comprise glucose oxidase or dehydrogenase (col. 24, ll. 27-28) and the mediator can comprise ferrocene (col. 15, ll. 32), quinones (col. 20, l. 50-col. 21, l. 15), ferricyanide (col. 22, l. 28) or ruthenium bipyridyl complexes (col. 15, ll. 33-38). Feldman does not disclose placing the enzyme and the mediator into the first conductive track. Gilmartin discloses that it is sometimes not desired to place the enzyme over the electrode and conductive track itself, but that the enzyme and the mediator should be incorporated into the ink itself. See col. 10, ll. 49-52. This would obviate the need for multiple coating steps (i.e. a

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separate coating of the enzyme layer would not be needed). Moreover, Feldman required the use of additional agents to prevent the enzyme layer from leaching off the electrode surface. See col. 24, ll. 33-43. Incorporating the enzyme into the ink would prevent such a leaching without the need for additional cross-linking agents. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Gilmartin for the biosensor of Feldman so as to obviate the need for multiple coating steps for the electrode as well as keeping the enzyme from leaching away. With respect to the enzyme and mediator being incorporated into the conductive track itself, Gilmartin would appear to utilize its ink for the deposition of both the working area of the electrodes (area C on fig. 1) and the connecting strip portion (area A of fig. 1). Moreover, Feldman also appears to deposit its conductive track at the same time as it deposits the metal portion of its electrode. See fig. 18A-18C and col. 31, ll. 8-25 of Feldman. Hence, if Feldman were to incorporate the enzyme and mediator into the electrode ink as rendered obvious by Gilmartin above, then the conductive track would also thereby contain both the enzyme and mediator.

5. With respect to the electrons being transferred from the enzyme directly to the at least one mediator, the teachings of Hedenmo and Karube evidence that the electron cycles for both glucose oxidase and glucose dehydrogenase read on the defined cycles. In particular, fig. 1 of Hedenmo shows for a glucose dehydrogenase-mediator system that electrons are being transferred from the enzyme to the mediator and to the working electrode. Karube shows for a glucose oxidase mediator electrode like Feldman that electrons are transferred from the enzyme to the mediator to the electrode. See the reaction diagram in col. 5.

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6. With respect to the various dependent claim limitations, see the discussion of Feldman and these limitations in the office action of 6-29-2005.

Response to Arguments

7. Applicant's arguments filed 8-16-2007 have been fully considered but they are not persuasive. As a preliminary note, the examiner has withdrawn the rejection relying on Hughes as a primary teaching to simplify the outstanding issues in this application. The teaching of Hughes appears to be analogous to the teaching of Feldman and the examiner sees little reason for maintaining separate rejections against both of these teachings. Applicant's arguments concerning Hughes are hereby moot in view of those withdrawn rejections. With respect to Feldman, applicant urges that Feldman gives no indication that the enzyme and mediator can be incorporated into the conductive track. Albeit true, this is the purpose of the secondary teaching of Gilmartin, which establishes that the enzyme can be deposited as a layer over the conductive track (like Feldman) could have also been incorporated into the conductive layer itself. See the rejection above. With respect to Gilmartin, applicant urges that it gives no teaching or suggestion of a direct transfer of electrons from the enzyme to the mediator could be accomplished if the enzyme and mediator are "intimately mixed" into the conductive track. It is unclear what the applicant is alluded to here. Feldman already disclosed intimately mixing the mediator and the enzyme together as would be required if one is to observe direct electron transfer between these two species. See col. 8, ll. 53-60 and note the "second electron transfer agent" is the enzyme itself (col. 24, ll. 24-27). The only distinction between this and the further suggestion of Gilmartin is that instead of utilizing an intimate mixture above conductive ink, one

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could have incorporated that intimate mixture into the conductive ink itself. Gilmartin gave no indication that changing the location of the enzyme affected its sensor performance so it is unclear why applicant believes that this would be a barrier to incorporation into Feldman as well.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Friday from 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
October 1, 2007


KAJ K. OLSEN
PRIMARY EXAMINER